

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

2013-1206

EXELA PHARMA SCIENCES, LLC, EXELA PHARMSCI, INC.,
and EXELA HOLDINGS, INC.,

Plaintiffs-Appellants,

v.

TERESA STANEK REA and UNITED STATES PATENT AND
TRADEMARK OFFICE,

Defendants-Appellees,

and

CADENCE PHARMACEUTICALS, INC. and
SCR PHARMATOP,

Intervenors.

Appeal from United States District Court for the Eastern District of
Virginia in Case No. 1:12-cv-469, Judge Liam O'Grady.

**REPLY BRIEF OF PLAINTIFFS-APPELLANTS EXELA PHARMA
SCIENCES, LLC, EXELA PHARMSCI, INC., AND EXELA
HOLDINGS, INC.**

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CERTIFICATE OF INTEREST

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1. The full name of every party or amicus represented by me is:

Exela Pharma Sciences, LLC, Exela PharmSci, Inc., and Exela Holdings, Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

Exela Pharma Sciences, LLC, Exela PharmSci, Inc., and Exela Holdings, Inc.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

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SUMMARY OF REPLY

The response briefs reveal a significant inconsistency. The U.S. Patent & Trademark Office (“PTO”) contends that the accrual date for purposes of the statute of limitation is the PTO’s 2003 revival decision. In contrast, Intervenor (“Pharmatop”) contend that the accrual date could be August 2006, when Pharmatop’s patent issued. Neither date comports with settled law for determining the accrual date under 28 U.S.C. § 2401(a).

The earliest possible date Exela could have brought its as-applied challenge under the Administrative Procedure Act (“APA”) was in 2011, when Pharmatop asserted its patent against Exela. The 2003 revival decision was an interlocutory, non-final agency action. Likewise, when the patent issued in 2006, Exela had not been harmed by the PTO’s unauthorized action. Once Pharmatop sued Exela for alleged infringement, Exela timely challenged the PTO’s unauthorized revival of Pharmatop’s patent application.

Moreover, Exela filed an as-applied challenge to a specific agency decision—the 2003 revival decision—because the PTO’s action contravened Congress’s strict limit on reviving abandoned international

patent applications. Exela did not seek to invalidate 37 C.F.R. § 1.137(b). Under the controlling statute, the PTO could have revived the application with a showing of “unavoidable abandonment,” but the PTO opted to ignore Congress’s mandate and revive Pharmatop’s application with a mere showing of “unintentional abandonment.” It is the PTO’s erroneous application of the “unintentional abandonment” standard to Pharmatop’s application that Exela challenges as contrary to law.

The remaining issue is whether a court can review the PTO’s *ultra vires* action. The PTO and Pharmatop contend that this Court’s precedent controls, citing *Aristocrat Technologies Australia Pty Ltd. v. International Game Technology*, 543 F.3d 657 (Fed. Cir. 2008), and *Pregis Corp. v. Kappos*, 700 F.3d 1348 (Fed. Cir. 2012). The present case is neither *Aristocrat* nor *Pregis*. Exela does not raise the PTO’s unauthorized action as an affirmative defense to infringement, as in *Aristocrat*. Similarly, unlike the obviousness-based APA claim in *Pregis*, Exela does not have any other avenue through which to challenge the PTO’s *ultra vires* action. Thus, *Aristocrat* and *Pregis* do not overcome the strong presumption of judicial review under the APA.

It was not Congress's intent to permit a private party to be injured by a patent issued only through unlawful PTO conduct. Congress established strict deadlines and standards for securing a patent right; missing those deadlines leads to the abandonment of the application, which can be revived only pursuant to the standard authorized by Congress. Exela's action is precisely the recourse contemplated by the APA to ensure that the public is not harmed by Pharmatop's improperly issued patent.

ARGUMENT

I. EXELA'S CAUSE OF ACTION IS TIMELY

First, regardless of whether the Court views Exela's APA claim as a facial challenge, Exela may now contest the validity of the PTO's revival decision as exceeding statutory authority. Even the Fourth Circuit's *Hire Order* decision recognizes the viability of subsequent challenges to the application of an agency ruling in such circumstances. *Second*, Exela's challenge is not a facial challenge to 37 C.F.R. § 1.137(b); Exela disputes only the propriety of the PTO's decision to revive Pharmatop's application based on a standard not permitted by statute. *Third*, the PTO tries to avoid the significance of the distinction

between a statute of limitations and a statute of repose. A statute of limitations, such as 28 U.S.C. § 2401(a), does not run until the claim has accrued, which in this case occurred when Pharmatop sued Exela for patent infringement in 2011.

A. The PTO And Pharmatop Acknowledge That A Party May Later Challenge An Agency Action When The Agency Acts Beyond Its Statutory Authority

The PTO tries to sidestep the seriousness of the unauthorized conduct at issue here. The PTO characterizes Exela's explanation of the PTO's *ultra vires* conduct as "particularly strange." PTO Br. 6 n.4. But there is nothing strange in providing statutory context when the alleged conduct involves agency action that violates a federal statute.

What is indeed strange is the PTO's decision to revive Pharmatop's patent application even though the controlling statute allows revival only when the abandonment was "unavoidable." *See* 35 U.S.C. § 371(d). Congress enacted § 371(d) for the express and limited purpose of permitting an applicant to revive an abandoned international application under specific conditions. More importantly, Congress codified the different circumstances available to different types of patent applications. *See, e.g.*, 35 U.S.C. § 111(a)(4). The

existence of the PTO's statutory violation underscores the seriousness of the district court's error. Indeed, no accepted theory of judicial review can condone an agency's action when that agency ignores the laws duly passed by Congress.

For this reason, courts have consistently held that a subsequent challenge to an agency action is not foreclosed when the agency's conduct is *ultra vires*. The Ninth Circuit's opinion in *Wind River Mining Corp. v. United States*, 946 F.2d 710 (9th Cir. 1991), provides perhaps the most cogent explanation of why Exela's APA challenge is timely.¹ In *Wind River*, a mining company had disputed the Bureau of Land Management's (BLM's) designation of certain land as a Wilderness Study Area (WSA), thus barring mining activities on the land. *Id.* at 711. BLM's designation had occurred in 1979, but the mining company did not challenge the designation in court until 1989. *Id.* at 711-12. BLM contended that the company's APA action was barred under the statute of limitations because it was more than six

¹ Surprisingly, the PTO's brief fails to address *Wind River*, and Pharmatop's brief does not even cite the case.

years after BLM's designation. *Id.* at 712. The Ninth Circuit disagreed, holding that the APA challenge was timely. *Id.* at 716.

The Ninth Circuit explained that a challenge based solely on a “procedural irregularity” differed significantly from one based on *ultra vires* conduct. *Id.* at 714-716 (“We think that different considerations guide the application of the statute of limitations to such challenges . . .”). The court appreciated the importance of finality, but nonetheless held that the finality interest was outweighed by the concern about an agency acting beyond its statutory powers. *Id.* The court explained that “[t]he government should not be permitted to avoid all challenges to its actions, even if *ultra vires*, simply because the agency took the action long before anyone discovered the true state of affairs.” *Id.* at 715; *see also North County Cmty. Alliance, Inc. v. Salazar*, 573 F.3d 738, 742-43 (9th Cir. 2009) (applying *Wind River* with approval and other exemplary cases).

Numerous other courts concur with the Ninth Circuit's holding that a subsequent challenge to an agency action is permitted when that action is not authorized by Congress. *See Wong v. Doar*, 571 F.3d 247, 263 n.15 (2d Cir. 2009) (citing *Wind River* with approval);

Dunn-McCampbell Royalty v. Nat'l Park Serv., 112 F.3d 1283, 1290 (5th Cir. 1997) (“[A] regulation initially unauthorized by statute cannot become authorized by the mere passage of time.”); *Public Citizen v. Nuclear Regulatory Comm’n*, 901 F.2d 147, 152 (D.C. Cir. 1990); *Commonwealth of Pa. Dep’t of Welfare v. U.S. Dep’t of Health & Human Servs.*, 101 F.3d 939, 944-47 (3d Cir. 1996) (Alito, J.); *Blanco v. United States*, 433 F. Supp. 2d 190, 197 (D.P.R. 2006) (noting that “courts have held that the Section 2401(a) six-year statute of limitations does not bar a challenge of an agency’s action when the affected party claims that the agency exceeded its statutory authority”); *Air India v. Brien*, 261 F. Supp. 2d 134, 138-39 (E.D.N.Y. 2003); *Alabama v. Shalala*, 124 F. Supp. 2d 1250, 1270 (M.D. Ala. 2000) (“[A] cause of action challenging a regulation based on the grounds that an agency exceeded its constitutional or statutory authority accrues when the agency applies the regulation to the specific challenger.”); *Florida Keys Citizens Coalition Inc. v. West*, 996 F. Supp. 1254, 1256 (S.D. Fla. 1998) (“Unlike procedural or facial attacks, a cause of action challenging the substantive application of a regulation may accrue well after the regulation was issued.”).

Notably, the Fourth Circuit's decision in *Hire Order Ltd. v. Marianos*, 698 F.3d 168 (4th Cir. 2012), does not upset this precedent, despite the PTO's suggestion to the contrary. Indeed, the Fourth Circuit cited with approval *Functional Music, Inc. v. FCC*, 274 F.2d 543 (D.C. Cir. 1958). In *Functional Music*, the D.C. Circuit held that a challenge to the FCC's rules could proceed even though the statutory time period for challenging the rules had expired. *Id.* at 546. The court explained that the "statutory time limit restricting judicial review of Commission action is applicable only to cut off review directly from the order promulgating a rule." *Id.* Importantly, a subsequent challenge to the rules was timely when there was *further agency action applying the rules*. *Id.* As the court noted, "limiting the right of review of the underlying rule would effectively deny many parties ultimately affected by a rule an opportunity to question its validity." *Id.*

Other cases cited in *Hire Order* stand for the same proposition. See *Bay Area Laundry & Dry Cleaning Pension Trust Fund v. Ferbar Corp. of Cal.*, 522 U.S. 192, 200-01 (1997); *Crown Coat Front Co. v. United States*, 386 U.S. 503, 519 (1967); *NLRB Union v. FLRA*, 834 F.2d 191, 195-96 (D.C. Cir. 1987); *Spannaus v. U.S. Dep't of Justice*, 824

F.2d 52, 56-57 (D.C. Cir. 1987). The PTO and Pharmatop avoid any analysis of these relevant cases.²

Accordingly, in assessing whether an APA challenge, premised on *ultra vires* conduct, is timely, the district court must determine whether the complaint is filed within six years of the date of accrual of the cause of action—not six years from the date of the rule promulgation or the agency decision.

B. Exela's Action Is An As-Applied Claim Challenging The PTO's Unauthorized Revival Of Pharmatop's Application—Not The Validity Of A PTO Rule

The district court's error in its reconsideration decision is predicated on a misinterpretation of Exela's APA challenge. The PTO and Pharmatop attempt to reinforce that error. When viewed correctly,

² After the Fourth Circuit's decision, Hire Order brought another APA challenge to the same regulation. *See Hire Order, Ltd. v. Herbert*, No. 12:cv-01908-CCK (D.D.C. filed Nov. 27, 2012). During that proceeding, the Government acknowledged that, "if an agency applies a regulation to the party in an enforcement proceeding, that party may challenge the validity of the regulation *even if the regulation was issued a long time ago*." *See* Defendant's Opposition to Plaintiff's Motion for Summary Judgment and Motion to Dismiss or, in the Alternative, Summary Judgment, *Hire Order*, No. 12:cv-01908-CCK, Dkt. No. 14 (D.D.C. filed Apr. 4, 2013) (emphasis added) (citing *Cellular Telecomms. & Internet Ass'n v. FCC*, 330 F.3d 502, 508 (D.C. Cir. 2003)).

Exela's complaint did not set forth a facial challenge but an as-applied challenge to the PTO's revival decision.

With a facial challenge, the party alleges that "the law is unconstitutional in all of its applications." *Wash. State Grange v. Wash. State Republican Party*, 552 U.S. 442, 449 (2008). To prevail on a facial challenge, "the challenger must establish that no set of circumstances exists under which the Act would be valid." *United States v. Salerno*, 481 U.S. 739, 745 (1987). Unlike an as-applied challenge, a facial challenge is divorced from the facts concerning the parties because the party does "not challenge its application in a particular instance." *Reno v. Flores*, 507 U.S. 292, 300 (1993); *see also Griffin v. Sec'y of Veterans Affairs*, 288 F.3d 1309, 1317 (Fed. Cir. 2002) ("Facial attacks on the discretion granted to a decisionmaker are not dependent on the facts surrounding any particular permit decision.").

First, the PTO ignores Supreme Court guidance when the PTO asserts that "no set of circumstances" test does not apply in the regulatory context. Specifically, the PTO suggests that, in assessing whether an APA claim is a "facial challenge," it is incorrect to apply the analysis set forth in *Salerno*, 481 U.S. at 745, *i.e.*, whether "no set of

circumstances exists under which the Act would be valid.” *See* PTO Br. 27. The PTO goes further and argues that such a standard is inconsistent with the Fourth Circuit’s decision in *Hire Order*. *Id.*

The PTO’s argument is remarkable, given the Supreme Court’s subsequent decision in *Flores*, 507 U.S. at 292. In *Flores*, the Court was analyzing the validity of certain regulations promulgated by the Immigration and Naturalization Service. *Id.* at 300-01. In doing so, the Court adopted the very same analysis: “To prevail in such a facial challenge, respondents ‘must establish that no set of circumstances exists under which the [regulation] would be valid.’” *Id.* at 301 (quoting *Salerno*, 481 U.S. at 745). In fact, if *Hire Order* is “inconsistent” with *Salerno*, as the PTO argues, then *Hire Order* must cede to Supreme Court precedent.

Notwithstanding the PTO’s and Pharmatop’s arguments, Exela has not facially challenged 37 C.F.R. § 1.137(b). In the complaint, Exela presented four counts. (A036-040.) Each count relied on the specific facts of the PTO’s revival decision. No count alleged that § 1.137(b) is facially invalid or has no lawful application otherwise. Rather, Exela’s complaint alleged that the PTO misapplied its rules and acted in direct

contravention to the statutory language of 35 U.S.C. § 371(d) when it revived Pharmatop's application.

The PTO and Pharmatop avoid the factually specific nature of Exela's challenge. Exela does not seek to invalidate § 1.137(b); instead, it seeks a remedy to the PTO's erroneous application of § 1.137(b) to the specific facts of Pharmatop's application. The error lies in the PTO's specific action, *i.e.*, reviving that specific abandoned international application under the "unintentional abandonment" standard, not that § 1.137(b) is invalid on its face.

Indeed, in *Tafas v. Dudas*, 541 F. Supp. 2d 805, 808 (E.D. Va. 2008), *aff'd in part, vacated in part on other grounds sub nom. by Tafas v. Doll*, 559 F.3d 1345 (Fed. Cir. 2009), the district court recognized that, "[b]ecause this case involves the legality of the Final Rules, a determination of their validity does not turn on facts unique to a particular plaintiff or on any disputes regarding such facts." Accordingly, the court did not need "to provide a lengthy factual background specific to the parties." *Id.*

The misfire in the PTO's attack is evident when considering the same facts present here, except assuming that 37 C.F.R. § 1.137(b) had

not been issued as a formal rule. Instead, assume the PTO simply revived an abandoned application under the aegis of the governing statute, 35 U.S.C. § 371(d). The PTO then would have revived Pharmatop's abandoned application, accepting Pharmatop's assertion of "unintentional abandonment." Exela again would have challenged that revival, alleging that it exceeded PTO's congressionally-mandated authority—in other words, the very same, as-applied APA challenge.

In this scenario, Exela's challenge would of course be a fact-specific challenge. It would not challenge the facial validity of any particular rule. It would instead dispute the propriety of the PTO's revival decision. In essence, Exela would bring the very same as-applied challenge as it does now.

The district court's error is further evident in its discussion about the apparent distinction between "which standard to apply" versus "how to apply a standard." (*See* A0004.) What Exela has always argued is that the PTO has failed in applying the 35 U.S.C. § 371(d) unavoidable standard, *i.e.*, the "how to apply a standard," by selecting a wrong rule, *i.e.*, the "which standard." Thus, even if the court's analysis based on

the “which” versus “why” distinction is valid, Exela’s argument that it is an as-applied challenge must prevail.

C. *Hire Order* Presented A Facial Challenge That Is Distinguishable From Exela’s Action

The PTO and Pharmatop rely extensively on *Hire Order*, but that reliance is misplaced. *Hire Order* differs from Exela’s APA challenge for several reasons, none of which the PTO or Pharmatop disputes.

First, the plaintiffs in *Hire Order* did not dispute that their complaint was a facial challenge to the Revenue Ruling. *See Hire Order*, 698 F.3d at 170 (stating that “Hire Order and Privott do not deny theirs is a facial challenge”). Thus, the panel in *Hire Order* had no reason to explore the precise contours of whether the plaintiffs’ complaint did in fact present a facial challenge to the rule.

More significantly, in *Hire Order*, there was no agency action that harmed the plaintiff. In fact, the agency had done nothing except issue the revenue ruling years earlier. *Id.* at 169. By their own assessment, the plaintiffs had not identified any specific conduct by the agency—or by any related party—that had harmed the plaintiffs. *Id.* At most, the plaintiffs claimed that they were refraining from certain conduct. *Id.*

In contrast, Exela has suffered significant harm resulting from the PTO's improper revival of Pharmatop's patent application. Exela has been sued for patent infringement, (A058-061; A076-093), which would not exist but for the PTO's improper revival. Exela has had to spend substantial resources defending itself in the patent infringement litigation. This damage to Exela occurred as a direct result of the PTO's unlawful conduct.

There are no similar facts in *Hire Order* where the plaintiffs alleged that the agency in question acted in excess of its authority in the specific instance. Further, there has been no case law support for the underlying premise that the fact that the regulation might have been applied consistently in other cases necessarily makes a challenge to it a facial challenge. The district court cited none.

Pharmatop also incorrectly argues that Exela's challenge cannot be "as-applied" because the PTO did not act directly against Exela. *See* Pharmatop Br. 25. Numerous decisions have permitted and approved of APA challenges to an agency decision when the agency decision was later determined to harm the party challenging the decision. Specifically, in *North County*, 573 F.3d at 740, the Ninth Circuit held as

timely an *ultra vires*-based challenge to the National Indian Gaming Commission's approval of the Nooksack Indian Tribe's gaming ordinance. The Commission approved the ordinance in 1993, but the plaintiff, a non-profit group, did not challenge the ordinance until 2007. *Id.* at 741. The court understood that the plaintiff was not affected by the 1993 agency action until 2006, when the Tribe began constructing a casino on its land. *Id.* at 743. Accordingly, the accrual date, for purposes of the statute of limitations, was 2006—not 1993—and therefore the plaintiff's APA challenge was not time barred. *Id.*³

The patent right granted to and asserted by Pharmatop is a direct extension of the PTO's revival decision. Thus, the PTO's actions are inextricably intertwined with Pharmatop's direct infringement action that has harmed Exela. In this way, Exela's injury is no different than the injury suffered by the non-profit organization in *North County*. Once the Tribe decided to exercise its rights granted to it by the agency, the harms suffered by the organization were attributable to the agency. In the patent context, Exela's harm is even more directly tied to the

³ Exela discussed *North County* in its opening brief, Exela Br. 38, yet neither the PTO nor Pharmtop respond to the analysis in that case.

PTO's improper revival, as the PTO always has the authority to reconsider *sua sponte* a grant of a patent right. *See* 35 U.S.C. § 304.

Moreover, it is not only the pleadings but also the remedy sought that determines whether the challenge is facial or as-applied. *See, e.g., Citizens United v. Fed. Election Comm'n*, 130 S. Ct. 876, 893 (2010) (explaining that the distinction between facial and as-applied challenges “is both instructive and necessary, for it goes to the breadth of the remedy employed by the Court, not what must be pleaded in a complaint”).

Contrary to statements made in Pharmatop's response, *see* Pharmatop Br. 29, Exela's requested remedy seeks only to overturn PTO's revival decision because it is contrary to § 371(d). Exela does not seek to invalidate § 1.137(b). This is analogous to *Bowen v. Kendrick*, 487 U.S. 489, 601 (1988), where the Court ordered “a remedy to insure that grants awarded by the Secretary comply with the Constitution and the statute.” Such a remedy here, as in *Bowen*, would not invalidate § 1.137(b) in all instances, but would narrowly prohibit the PTO from applying the rule in a manner contrary to the statute. This narrower relief distinguishes Exela's as-applied challenge from a broader facial

challenge. Accordingly, the district court's decision to dismiss Exela's claim as being an untimely facial challenge under *Hire Order* must be reversed.

D. The Distinction Between A Statute Of Repose And A Statute Of Limitations Is Important

The PTO suggests that the distinction between a statute of repose and a statute of limitations is insignificant, calling it a “straw man.” PTO Br. 20 n.10. Rather than address the merits, the PTO resorts to this clichéd response.

Multiple courts have distinguished between a statute of repose and a statute of limitations. *See, e.g., City of Pontiac Gen. Employees' Retirement System v. MBIA, Inc.*, 637 F.3d 169, 175 (2d Cir. 2011) (noting the difference in the “basic purpose” of a statute of repose compared to a statute of limitations); *see also Ma v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 597 F.3d 84, 88 n.4 (2d Cir. 2010) (observing that, although “[s]tatutes of repose and statutes of limitation are often confused[,] . . . they are [nonetheless] distinct”); *McCann v. Hy-Vee, Inc.*, 663 F.3d 926, 930 (7th Cir. 2011).

This Court likewise has held that a statute of repose is not the same as a statute of limitations. *See, e.g., Regents of Univ. of Cal. v.*

Univ. of Iowa Research Found., 455 F.3d 1371, 1376 (Fed. Cir. 2006) (describing 35 U.S.C. § 135(b) as a statute of repose); *Weddel v. Sec’y of Health & Human Servs.*, 100 F.3d 929, 932 (Fed. Cir. 1996) (holding that Section 16(a) of the Vaccine Act is “a statute of repose rather than a statute of limitations” and thus equitable tolling was not available).

If § 2401(a) were a statute of repose, the deadline for challenging an agency’s action would simply—and always—be six years from the agency’s action, regardless of when the harm to the challenger accrued. But § 2401(a) is not written in this manner. It is a statute of limitations, and therefore, under the “standard rule,” the critical date is when the party’s claim has accrued, *i.e.*, the date when the plaintiff has a “complete and present cause of action.” *Bay Area Laundry*, 522 U.S. at 195; *Crown Coat*, 386 U.S. at 510-11 (explaining that “the ‘right of action’ of which § 2401(a) speaks is not the right to administrative action but the right to file a civil action in the courts against the United States”); *Hair v. United States*, 350 F.3d 1253, 1260 (Fed. Cir. 2003) (“The earliest opportunity for a complete and present cause of action is that moment when the plaintiff has suffered a legally recognizable harm at the hands of the defendant”); *United States v. Minor*,

228 F.3d 352, 359 (4th Cir. 2000) (“The cause of action can accrue not earlier than the date that forfeiture actually occurred, because until that date the owner has not actually incurred the specific injury alleged.”); *United States v. Commodities Export Co.*, 972 F.3d 1266, 1270 (Fed. Cir. 1992) (“[A] cause of action accrues when all events necessary to state a claim have occurred.”).

Neither the PTO nor Pharmatop explains how Exela could have had a viable cause of action in 2003 when the PTO revived the patent application.⁴ At that point, the PTO had not granted any exclusive right to Pharmatop. Nor could Pharmatop have sued Exela for patent infringement. Similarly, Exela did not have a cause of action when Pharmatop’s patent issued in 2006. Even at that time, Exela suffered no injury because Pharmatop had not asserted the patent against any party, let alone Exela.

It is axiomatic, moreover, that a right of action against an agency cannot accrue until the agency’s action is final. *Bennett v. Spear*, 520

⁴ The PTO contends that “Exela’s claims accrued, *at latest*, in 2003, when the USPTO revived SCR’s international patent application.” PTO Br. 34 (emphasis added). Pharmatop, however, argues that the accrual date could be 2006, when the patent issued.

U.S. 154, 177-78 (1997). In determining whether a particular agency action is final, “[t]he core question is whether the agency has completed its decisionmaking process, and whether the result of that process is one that will directly affect the parties.” *Franklin v. Massachusetts*, 505 U.S. 788, 797 (1992). To be a “final agency action,” it must be a “definitive statement[] of [the agency’s] position” having a “direct and immediate” consequence. *FTC v. Standard Oil Co.*, 449 U.S. 232, 241 (1980); *see also Wollman v. Geren*, 603 F. Supp. 2d 879, 885 (E.D. Va. 2009) (stating that a final agency action “usually require[s] some positive action on the part of the affected party or a concrete and immediately-felt harm”).

The PTO’s 2003 revival decision is a classic interlocutory decision. *Cf. Mikkilineni v. Stoll*, 410 Fed. App’x 311, 312 (Fed. Cir. 2010) (non-precedential). The PTO could have rejected Pharmatop’s application for a host of other reasons. Additionally, Pharmatop could have abandoned the patent application or failed to pay the requisite fees prior to issuance. Simply put, when the PTO revived the application in 2003, the PTO had not completed its decisionmaking process on the potential granting of the application, and the revival did

not have any “direct and immediate” consequence to Exela or any other entity. The PTO and Pharmatop do not identify a single precedent supporting their contentions that the 2003 revival decision is a final agency action.

II. THE DISTRICT COURT CORRECTLY RULED THAT IT CAN REVIEW THE PTO’S *ULTRA VIRES* REVIVAL OF PHARMATOP’S APPLICATION

In arguing that reviewability is precluded, the PTO relies primarily on *Aristocrat*, whereas Pharmatop relies primarily on *Pregis*. Neither *Aristocrat* nor *Pregis* precludes Exela’s action, however. Moreover, given the lack of any other recourse for challenging the PTO’s impermissible conduct, the strong presumption of reviewability under the APA has not been rebutted.

A. *Aristocrat* Does Not Address The Viability Of An APA Claim Such As Exela’s Challenge

The PTO relies primarily on *Aristocrat*. *See* PTO Br. 36-42. Yet, *Aristocrat* is unavailing to the PTO’s argument. As an initial point, the issue in *Aristocrat* was framed concisely by the Court: “The salient question, then, is whether improper revival is ‘made a defense’ by title 35.” 543 F.3d at 662. *Aristocrat* held that improper revival was not a defense under § 282—no more.

The PTO, in reading *Aristocrat*, seizes on language expressed in the context of the specific issue in that case: The types of defenses available under 35 U.S.C. § 282. But *Aristocrat* held no further, for there was no occasion to examine whether the improper revival of a patent application could be a basis for an APA claim.

Furthermore, the PTO's willful contravention of a federal statute is far different than the purported "prosecution irregularities" in *Magnivision, Inc. v. Bonneau Co.*, 115 F.3d 956 (Fed. Cir. 1997), which was cited in *Aristocrat*. In *Magnivision*, "[t]he principal 'prosecution irregularity' asserted by Bonneau was the patent examiner's failure to record the substance of a telephone call that the examiner made to Magnivision's attorney." *Id.* at 958. Certainly, the APA was not crafted to cover failures of an agency employee to record the substance of a telephone conversation. But when the PTO orders an abandoned patent application to be revived—in direct contravention of statutory law—this is no simple prosecution "irregularity." It would be an extraordinary outcome, indeed, to conclude that the PTO's violation of federal law is a minor "irregularity" or "lapse."

B. Unlike The Present Challenge, *Pregis* Involved An Obviousness Challenge Repurposed As An APA Claim

Unlike the PTO, Pharmatop relies primarily on *Pregis* in arguing that judicial review is precluded. *See* Pharmatop Br. 43-49. *Pregis* is distinguishable, however, for at least two reasons.

First, in *Pregis*, this Court held “that a third party cannot sue the PTO under the APA to challenge a PTO decision to issue a patent.” 700 F.3d at 1357. The plaintiffs in *Pregis* challenged “two distinct aspects of a PTO ‘decision to issue’ a patent”: “1) the PTO’s stated reasons for allowing the claims during examination under 35 U.S.C. § 131, and 2) the issuance of the patent itself.” *Id.* at 1356.

Unlike the APA challenge in *Pregis*, Exela does not seek to raise issues available through a defense under 35 U.S.C. § 282. Indeed, the plaintiff in *Pregis* raised essentially the same set of facts supporting its invalidity defense in the same infringement action. *See* 700 F.3d at 1356-57. In rejecting the propriety of such an APA claim, this Court stated that the Patent Act reflects the intention of Congress “not to provide for third parties to obtain review of *the reasons for allowance* of claims.” *Id.* at 1359 (emphasis added).

Unlike *Pregis*, Exela does not challenge the PTO's stated reasons for allowing the claims of Pharmatop's patent in this APA case. Instead, Exela asks for the reversal of the PTO's revival of Pharmatop's abandoned application. Exela's challenge has nothing to do with the validity of the '218 patent and does not disturb the "carefully balanced framework of the Patent Act." *Id.* at 1359. *Pregis* was consistent with Congressional intent that there be a "remedy for every legal wrong" because Congress provided an alternative remedy in § 282 of the Patent Act.

Second, although the plaintiffs in *Pregis* had "adequate remedies," which precluded judicial review, such adequate remedies are not available here. In *Pregis*, this Court identified "three adequate remedies in court for competitors harmed by the PTO's erroneous issuance of a patent." *Id.* at 1359-1360. These remedies were identified as (1) *inter partes* reexamination, (2) raising invalidity as a defense to a patent suit under § 282, and (3) "proactively bringing a declaratory judgment against the patent owner to have the patent declared invalid." *Id.* at 1360. None of these remedies are available in this case. Improper revival is not a basis for instituting a reexamination. And

Aristocrat foreclosed the possibility of raising “improper revival” as a defense under § 282 of the Patent Act. Thus, unlike the plaintiffs in *Pregis*, Exela has no other adequate remedy or even “relief of the ‘same genre’” available. 700 F.3d at 1360.

A fundamental principle of the APA is that a party with no other adequate remedy is entitled to judicial review of a final agency decision. *See* H.R. Rep. No. 1980, at 41 (1946) (explaining that the APA was intended to “afford a remedy for every legal wrong”). As such, *Pregis* does not bar judicial review of Exela’s claim. Although precluding judicial review in *Pregis* was consistent with Congressional desire to have a “remedy for every legal wrong,” precluding judicial review in this case would leave Exela with no remedy at all—a result inconsistent with the legislative history of both the APA and Patent Act. Denying review here would also ignore the strong presumption of reviewability embodied in a long history of controlling Supreme Court case law. *See infra*.

C. The Presumption Of Reviewability Under The APA Has Not Been Rebutted And Is In Fact Consistent With The Patent Act

Unless a statute indicates otherwise, the APA is presumed to ensure judicial review to a party aggrieved by an agency. Indeed, “[t]he Administrative Procedure Act provides specifically not only for review of ‘[a]gency action made reviewable by statute’ but also for review of ‘final agency action for which there is no other adequate remedy in a court.’” *Abbott Labs. v. Gardner*, 387 U.S. 136, 140 (1967) (quoting 5 U.S.C. § 704). Here, neither the text nor the structure of the Patent Act overcomes the presumption that courts can rein in an agency’s unauthorized conduct.

The PTO and Pharmatop concede that the Patent Act does not expressly preclude judicial review. Further, the PTO and Pharmatop do not identify any relevant legislative history that would evince Congress’s intent to preclude judicial review of the PTO’s unauthorized application revival.

Although the legislative history of 35 U.S.C. § 371(d) is silent on judicial review, the legislative histories of the APA and 1952 Patent Act evince Congress’s clear intent to ensure judicial review when an

individual was wronged by an agency decision. *Bowen v. Massachusetts*, 487 U.S. 879, 903 (1988) (holding that the “central purpose” of the APA is “providing a broad spectrum of judicial review of agency action”).

When enacted, Section 10 of the APA provided that “[a]ny person suffering legal wrong because of any agency action, or adversely affected or aggrieved by such action within the meaning of any relevant statute, shall be entitled to judicial review thereof.” Administrative Procedure Act § 10(a), 60 Stat. 237, 243 (1946). Additionally, the APA commanded that “[e]very agency action made reviewable by statute and every final agency action for which there is no other adequate remedy in any court shall be subject to judicial review.” *Id.* § 10(c), 60 Stat. at 243. Thus, the text of the APA itself established the broad presumption of reviewability.

This presumption of reviewability is also evident in the APA’s legislative history. In the House Report preceding the APA’s passage, the Committee on the Judiciary summarized Section 10’s judicial review provision as follows:

This section confers a right of review upon any person adversely affected in fact by agency action or aggrieved

within the meaning of any statute. The phrase “legal wrong” means such a wrong as is specified in section 10(e). It means that something more than mere adverse personal effect must be shown in order to prevail—that is, that the adverse effect must be an illegal effect. Almost any governmental action may adversely affect somebody—as where rates or prices are fixed—but a complainant, in order to prevail, must show that the action is contrary to law in either substance or procedure. The law so made relevant is not only constitutional law but any and all applicable law.

H.R. Rep. No. 1980 at 276. With little doubt, Congress intended that the APA review provisions serve as a check on unlawful agency action.

Shortly after passage of the APA, the then-Commissioner of Patents, Casper Ooms, further explained the applicability of Section 10’s judicial review. *See* Casper W. Ooms, *The United States Patent Office and the Administrative Procedure Act*, 38 Trademark Reporter 149 (1948) (available at A210). Commissioner Ooms explained that “the enactment of Section 10 will have the effect of minimizing the technical aspects of the review and its availability, and that the courts will welcome the appellant as exercising a right of review and not merely treat him as a suppliant for extraordinary remedy.” *Id.* at 159. In other words, Commissioner Ooms viewed the APA as providing an enhanced avenue for the administrative review of certain PTO decisions.

After passage of the APA, Commissioner Ooms believed that petition decisions were reviewable under the APA. In fact, during Commissioner Ooms' testimony before Congress, he explained that, in challenging a petition to revive, "[t]he only review available under the Administrative Procedure Act will be by way of a proceeding in the nature of a mandamus, although it will probably no longer be called such, which will, of course, give relief only where the discretion had been abused." *Id.* at 160. Importantly, Commissioner Ooms expected courts to "welcome the appellant as exercising a right of review and not merely treat him as a suppliant for extraordinary remedy." *Id.*

Similar to the APA's legislative history, when Congress considered the bill that led to the Patent Act of 1952, the House Judiciary Committee also recognized the general availability of judicial review under the APA. *See* H.R. Rep. No. 1923, at 7-8 (1952). The Committee noted the two types of appeal available to an application: appeal to an appeals court, or file suit in district court. *Id.* At the same time, the Committee emphasized that the statutory sections relating to Patent Office review "makes no fundamental change in the various appeals and *other review* of Patent Office action." *Id.* (emphasis added). Thus,

Congress acknowledged, by reference to “other review,” that judicial review of the PTO was not foreclosed by the Patent Act.

Exela’s right to judicial review is clear in view of the legislative history of both the APA and the Patent Act. The PTO and Pharmatop provide no legitimate rationale to disregard Congress’s intention of providing “a remedy for every legal wrong.” H.R. Rep. No. 1980, at 41.

Additionally, the overall structure and purpose of the Patent Act do not completely override the broad grant of judicial review under the APA. Contrary to Pharmatop’s argument, Exela lacks an adequate remedy to cure the harm suffered by the PTO’s improper revival. Specifically, in *Pregis*, this Court identified three purportedly-adequate remedies suggesting that APA judicial review was not necessary: (1) *inter partes* reexamination, (2) raising invalidity as a defense to a patent suit under § 282, and (3) “proactively bringing a declaratory judgment against the patent owner to have the patent declared invalid.” *Id.* at 1360.

None of these remedies is available to Exela. *Inter partes* reexamination cannot be used to challenge unauthorized PTO decision to revive Pharmatop’s patent application. *See* 35 U.S.C. § 311.

Inter partes reexaminations are generally restricted to matters concerning the patentability of particular claims. As to the second and third remedies, neither can be the basis for providing an “adequate remedy.” As noted above, *Aristocrat* foreclosed the possibility of raising “improper revival” as a defense under § 282. Accordingly, unlike the plaintiffs in *Pregis*, 700 F.3d at 1360, Exela has no other adequate remedy or even “relief of the ‘same genre’” available.

Judicial review “is essential to the integrity of our system of government; it is ‘the necessary premise of legal validity.’” *Patlex Corp. v. Mossinghoff*, 771 F. 2d 480, 482 (Fed. Cir. 1985). Indeed, “[j]udicial review of administrative action also serves to protect and preserve the separation of powers, a function clarified early in our nation’s history.” *Id.* Absent judicial review, the PTO will be free to ignore congressionally-mandated limitations on its authority.

III. TO THE EXTENT THE LAW DIFFERS, FEDERAL CIRCUIT LAW SHOULD CONTROL

Finally, both the PTO and Pharmatop place extraordinary emphasis on its contention that Fourth Circuit law should control question of whether Exela’s challenge to the PTO’s revival of a patent application is timely. Exela submits that their reliance is misplaced.

As a first point, Exela has never argued that Fourth Circuit law should govern to the exclusion of Federal Circuit law. Instead, Exela submits that, as to this issue, there is no difference between Fourth Circuit law and Federal Circuit law, when *Hire Order* is correctly understood.

If this Court discerns a difference, however, Exela submits Federal Circuit law should govern an issue so integrated with patent law and the function of the PTO. The parties agree that jurisdiction before this Court is based on a substantial question of patent law. *See* PTO Br. 1 (“This Court has jurisdiction under 28 U.S.C. § 1295(a)(1).”). Indeed, “Federal Circuit law applies to ‘issues of substantive patent law and certain procedural issues pertaining to patent law.’” *Pregis*, 700 F.3d at 1353 (quoting *Research Corp. Techs., Inc. v. Microsoft Corp.*, 536 F.3d 1247, 1255 (Fed. Cir. 2008)).

The PTO and Pharmatop cite only one case, *Landmark Screens, LLC v. Morgan, Lewis, & Bockius, LLP*, 676 F.3d 1354 (Fed. Cir. 2012), to support their contention that the Fourth Circuit law exclusively controls. But that case did not involve an APA challenge concerning a patent-related decision of the PTO. Instead, *Landmark Screens*

concerned a statute of limitations in the context of a state-law fraud claim brought under California law. *Id.* at 1362.

IV. THE PTO SHOULD BE COMPELLED TO ADDRESS EXELA'S PETITION

In its petition, Exela sought to invoke the Director's supervisory authority to review PTO conduct that violated § 371 and that also failed to conform to PTO regulations, *e.g.*, 37 C.F.R. § 1.495(b), (c). Exela does not argue, as suggested by Pharmatop, that the Director must necessarily agree with the arguments made in its petition. Instead, Exela explains that the Director was required to consider Exela's arguments as part of the Director's general duty to "provide policy direction and management supervision for the Office and for the issuance of patents." 35 U.S.C. § 3(a)(2)(A). The PTO's refusal to consider Exela's petition based on standing was an abuse of discretion because it ignored the fact that the Director's supervisory responsibility is independent of the party seeking review.

Moreover, as the district court properly found, Exela did have standing to raise the issue of improper revival. (*See* A010-011.) The PTO's other reasons for refusing to consider Exela's petition were simply not credible given that the standards for information submission

that Exela allegedly failed to comply with were completely unrelated. Whatever the merits of Exela's petition, the Director does not have the discretion to allow the agency to misapply its own regulations and ignore federal statutes. *See Service v. Dulles*, 354 U.S. 363, 372 (1957) (stating "regulations validly prescribed by a government administrator are binding upon him as well as the citizen, and that this principle holds even when the administrative action under review is discretionary in nature"). The PTO should be required to consider Exela's petition on the merits.

V. CONCLUSION

The district court's dismissal should be reversed.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this day, October 15, 2013, the foregoing REPLY BRIEF OF PLAINTIFFS-APPELLANTS EXELA PHARMA SCIENCES, LLC, EXELA PHARMSCI, INC., AND EXELA HOLDINGS, INC., was electronically filed and therefore served electronically via the court's ECF/CM system on the following counsel:

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 28.1(e). The brief contains 6,887 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

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